Hearing Date and Time: March 21, 2023, at 11:00 a.m. (prevailing Eastern Time)
Objection Date and Time: March 14, 2023, at 4:00 p.m. (prevailing Eastern Time)

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UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	**Chapter 11**
PURDUE PHARMA L.P., *et al.*,	**Case No. 19-23649 (SHL)**
Debtors.[1]	**(Jointly Administered)**

NOTICE OF HEARING REGARDING MOTION OF DEBTORS FOR AUTHORIZATION TO ENTER INTO FUNDING AGREEMENT

PLEASE TAKE NOTICE that on February 28, 2023, the above-captioned debtors and debtors in possession (collectively, the "**Debtors**") filed the *Amended Motion of Debtors for Authorization to Enter into Funding Agreement* (the "**Motion**"). A hearing on the Motion will be held on **March 21, 2023, at 11:00 a.m. (prevailing Eastern Time)** (the "**Hearing**") before the

[1] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

Honorable Sean H. Lane, United States Bankruptcy Judge, United States Bankruptcy Court for the Southern District of New York, 300 Quarropas Street, White Plains, New York 10601 (the "**Bankruptcy Court**"), or at such other time as the Bankruptcy Court may determine.

PLEASE TAKE FURTHER NOTICE that pursuant to General Order M-543, dated March 20, 2020 (Morris, C.J.) ("**General Order M-543**"), the Hearing shall be conducted **via Zoom for Government®** so long as General Order M-543 is in effect or unless otherwise ordered by the Bankruptcy Court.[2]

PLEASE TAKE FURTHER NOTICE that the Hearing may be continued or adjourned thereafter from time to time without further notice other than an announcement of the adjourned date or dates at the Hearing or a later hearing. The Debtors will file an agenda before the Hearing, which may modify or supplement the motions to be heard at the Hearing.

PLEASE TAKE FURTHER NOTICE that any responses or objections (the "**Objections**") to the Motion shall be in writing, shall conform to the Federal Rules of Bankruptcy Procedure and the Local Bankruptcy Rules for the Southern District of New York, shall be filed with the Bankruptcy Court (a) by attorneys practicing in the Bankruptcy Court, including attorneys admitted *pro hac vice*, electronically in accordance with General Order M-399 (which can be found at www.nysb.uscourts.gov), and (b) by all other parties in interest, on a CD-ROM, in text-searchable portable document format (PDF) (with a hard copy delivered directly to Chambers), in accordance with the customary practices of the Bankruptcy Court and General Order M-399, to the extent applicable, and shall be served in accordance with the *Second Amended Order Establishing Certain Notice, Case Management, and Administrative Procedures* entered on

[2] A copy of General Order M-543 can be obtained by visiting http://www.nysb.uscourts.gov/news/court-operations-under-exigent-circumstances-created-covid-19.

November 18, 2019 [ECF No. 498], so as to be filed and received no later than **March 14, 2023** at **4:00 p.m.** (prevailing Eastern Time) (the "**Objection Deadline**").

PLEASE TAKE FURTHER NOTICE that if no Objections are timely filed and served with respect to the Motion, the Debtors may, on or after the Objection Deadline, submit to the Bankruptcy Court an order substantially in the form of the proposed order annexed to the Motion, which order may be entered without further notice or opportunity to be heard.

PLEASE TAKE FURTHER NOTICE that objecting parties are required to attend the Hearing, and failure to appear may result in relief being granted upon default; *provided* that objecting parties shall attend the Hearing via Zoom for Government so long as General Order M-543 is in effect or unless otherwise ordered by the Bankruptcy Court.

PLEASE TAKE FURTHER NOTICE that copies of the Motion may be obtained free of charge by visiting the website of Kroll Restructuring Administration at https://restructuring.ra.kroll.com/purduepharma. You may also obtain copies of any pleadings by visiting the Bankruptcy Court's website at http://www.nysb.uscourts.gov in accordance with the procedures and fees set forth therein.

Dated: February 28, 2023
New York, New York

DAVIS POLK & WARDWELL LLP

By: */s/ Eli J. Vonnegut*

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UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	**Chapter 11**
PURDUE PHARMA L.P., *et al.*,	**Case No. 19-23649 (SHL)**
Debtors.[3]	**(Jointly Administered)**

MOTION OF DEBTORS FOR AUTHORIZATION
TO ENTER INTO FUNDING AGREEMENT

[3] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

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Purdue Pharma L.P. ("**PPLP**") and its affiliates that are debtors and debtors in possession in these proceedings (collectively, the "**Debtors**") respectfully state as follows:

Relief Requested

1. By this Motion (the "**Motion**"), and pursuant to sections 105(a) and 363(b) of the United States Code, 11 U.S.C. § 101, *et seq*. (as amended or modified, the "**Bankruptcy Code**"), the Debtors seek entry of an order, substantially in the form attached hereto as **Exhibit A** (the "**Order**"), authorizing the Debtors to enter into and perform under a funding agreement (the "**2023 HRT Agreement**") by and between PPLP and Harm Reduction Therapeutics, Inc. ("**HRT**"), substantially in the form attached hereto as **Exhibit B**, and to provide HRT with up to $9 million of additional funding to enable HRT to prepare for production, marketing and distribution of a lower-cost, over-the-counter ("**OTC**") naloxone nasal spray device designed to reverse the effects of an opioid overdose.

Jurisdiction and Venue

2. The United States Bankruptcy Court for the Southern District of New York (the "**Court**") has jurisdiction to consider this matter pursuant to 28 U.S.C. §§ 157 and 1334 and the Amended Standing Order of Reference M-431, dated January 31, 2012 (Preska, C.J.). This is a core proceeding pursuant to 28 U.S.C. § 157(b)(2) and, pursuant to Rule 7008 of the Federal Rules of Bankruptcy Procedure (the "**Bankruptcy Rules**"), the Debtors consent to entry of a final order by the Court in connection with this Motion to the extent that it is later determined that the Court, absent consent of the parties, cannot enter a final order or judgment consistent with Article III of the United States Constitution.

3. Venue is proper before the Court pursuant to 28 U.S.C. §§ 1408 and 1409.

General Background

4. On September 15, 2019 (the "**Petition Date**"), the Debtors each commenced with this Court a voluntary case (collectively, the "**Cases**") under chapter 11 of the Bankruptcy Code. The Debtors are authorized to operate their businesses and manage their properties as debtors in possession pursuant to sections 1107(a) and 1108 of the Bankruptcy Code. On September 27, 2019, the United States Trustee for the Southern District of New York appointed the official committee of unsecured creditors (the "**Creditors' Committee**"). No trustee has been appointed in these Cases.

5. On June 25, 2020, the Court entered an order [ECF No. 1301] (the "**2020 HRT Order**") granting the *Amended Motion of Debtors for Authorization to Enter into Funding Agreement* [ECF No. 1249] (the "**2020 HRT Motion**") and authorizing the Debtors to provide up to $6.5 million to HRT under that certain Funding Agreement, dated as of June 25, 2020, by and between PPLP and HRT (the "**2020 HRT Agreement**").

6. On March 23, 2022, the Court entered an order [ECF No. 4588] (the "**2022 HRT Order**") granting the *Motion of Debtors for Authorization to Enter into Amended and Restated Funding Agreement* [ECF No. 4407] (the "**2022 HRT Motion**" and, together with the 2020 HRT Motion, the "**Prior HRT Motions**") and authorizing the Debtors to provide up to $11 million to HRT under that certain Amended and Restated Funding Agreement, dated as of March 22, 2022, by and between PPLP and HRT (the "**2022 HRT Agreement**" and, together with the 2020 HRT Agreement, the "**Prior HRT Agreements**").

7. Additional information about the Debtors' businesses and the events leading up to the Petition Date can be found in the *Debtors' Informational Brief* filed on September 16, 2019 [ECF No. 17].

Preliminary Statement

8. Naloxone is an opioid antagonist "rescue drug" that can counter the effects of an opioid overdose. According to the Centers for Disease Control and Prevention, over 80,000 lives were lost to opioid overdoses in 2021.[4] Thousands of overdose deaths could be prevented if individuals, families, first responders and communities had greater access to naloxone.[5] However, two substantial barriers to access to this potentially life-saving medication—price and the need for a prescription—stand in the way. The development and introduction of OTC naloxone products promises to meaningfully reduce both of these barriers.

9. The American Medical Association,[6] the current[7] and prior[8] United States Surgeons General, and both past[9] and current[10] FDA Commissioners have all called for greater

[4] Centers for Disease Control and Prevention, *U.S. Overdose Deaths in 2021 Increased Half as Much as in 2020 – But Are Still Up 15%* (May 11, 2022), https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm.

[5] *See* Centers for Disease Control and Prevention, Featured Topics: *Save Lives Now*, https://www.cdc.gov/drugoverdose/featured-topics/save-lives-now.html.

[6] Letter from James L. Madara, MD, Am. Med. Ass'n, to the Hon. Rahul Gupta, MD, Dir., White House Office of Nat'l Drug Control Policy (Feb. 15, 2022), https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2022-2-15-Letter-to-Gupta-re-ONDCP-Naloxone.pdf.

[7] Press Briefing, *Excerpts from Dr. Gupta's Remarks at Ceremonial Swearing in at the White House* (Nov. 19, 2021), https://www.whitehouse.gov/ondcp/briefing-room/2021/11/19/excerpts-from-dr-guptas-remarks-at-ceremonial-swearing-in-at-the-white-house/.

[8] *U.S. Surgeon General's Advisory on Naloxone and Opioid Overdose*, HHS.gov, https://www.hhs.gov/surgeongeneral/reports-and-publications/addiction-and-substance-misuse/advisory-on-naloxone/index.html.

[9] U.S. Food & Drug Admin., FDA Statement, Statement from FDA Commissioner Scott Gottlieb, M.D., on unprecedented new efforts to support development of over-the-counter naloxone to help reduce opioid overdose deaths (Jan. 17, 2019), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-unprecedented-new-efforts-support-development-over; U.S. Food & Drug Admin., FDA Statement, Statement on continued efforts to increase availability of all forms of naloxone to help reduce opioid overdose deaths (Sept. 20, 2019), https://www.fda.gov/news-events/press-announcements/statement-continued-efforts-increase-availability-all-forms-naloxone-help-reduce-opioid-overdose.

[10] U.S. Food & Drug Admin., *Remarks by FDA Commissioner Robert Califf to the 2022 Rx and Illicit Drug Summit* (Apr. 20, 2022), https://www.fda.gov/news-events/speeches-fda-officials/remarks-fda-commissioner-robert-califf-2022-rx-and-illicit-drug-summit-04202022.

access to naloxone. Recent actions taken by the FDA further evidence its commitment to improving naloxone access. In August of 2022, the FDA Commissioner Robert Califf introduced the FDA Overdose Prevention Framework – FDA's "vision to undertake impactful, creative actions to prevent drug overdoses and reduce deaths." Among other priorities, the framework encourages expanding availability and access to overdose reversal products, including naloxone, by supporting accelerated review of products and exploring over-the-counter access.[11] In November of 2022, the FDA issued a Federal Register notice that included a preliminary assessment that certain naloxone drug products may be approvable as safe and effective for nonprescription use.[12] This unprecedented step by the FDA was intended by the agency to "facilitate development and approval of nonprescription naloxone products."[13] Just this month, the FDA issued a public update on its significant efforts to widen naloxone access.[14] In other words, the need for OTC naloxone is clear, unambiguous, and strongly supported as a safe and effective way to combat opioid overdose deaths.

10. HRT is a non-stock Maryland tax exempt 501(c)(3) pharmaceutical company founded in 2017 whose mission is to prevent opioid overdose deaths by making easy-to-use, low-cost naloxone available over the counter. In June of 2020 and again in March of 2022, the Debtors

[11] FDA News Release, Robert M. Califf, M.D., Comm'r of Food and Drugs, *FDA's Overdose Prevention Framework Aims to Prevent Drug Overdoses and Reduce Death* (Aug. 30, 2022), https://www.fda.gov/news-events/fda-voices/fdas-overdose-prevention-framework-aims-prevent-drug-overdoses-and-reduce-death.

[12] *E.g.*, FDA News Release, *FDA Announces Preliminary Assessment that Certain Naloxone Products Have the Potential to be Safe and Effective for Over-the-Counter Use* (Nov. 15, 2022), https://www.fda.gov/news-events/press-announcements/fda-announces-preliminary-assessment-certain-naloxone-products-have-potential-be-safe-and-effective.

[13] *Id*.

[14] Marta Sokolowska, Ph.D., CDER Deputy Ctr. Dir., U.S. Food & Drug Admin., *From Our Perspective, CDER's Continued Efforts to Widen Naloxone Access* (Feb. 2, 2023), https://www.fda.gov/drugs/news-events-human-drugs/our-perspective-cders-continued-efforts-widen-naloxone-access?utm_medium=email&utm_source=govdelivery.

received Court approval to fund HRT's development of its life-saving product (brand name RiVive™), in an aggregate amount of $17.5 million, subject to HRT achieving a series of milestones.[15] With this support, HRT was able to, among other things, successfully execute a clinical trial showing that RiVive is absorbed as quickly as the FDA reference product, engage a contract manufacturer to produce the product, and complete other stability and reliability studies and reports required for its New Drug Application ("**NDA**"), and submit the NDA for RiVive to the FDA. The FDA accepted the NDA in December of 2022 and granted it Priority Review status, accelerating the FDA review process from 10 to 6 months. HRT expects a decision from the FDA regarding the review of the RiVive NDA by the end of July 2023.[16] With third-party financial support, HRT believes that RiVive can be available for distribution and commercial sale in early 2024.

11. The Debtors believe that RiVive will serve an important role in treating opioid overdoses for years to come. There have been significant developments in the OTC naloxone landscape over the past twelve months. In December of 2022, Emergent BioSolutions announced FDA acceptance of a supplemental New Drug Application to switch its prescription nasal spray product, Narcan®, to over-the-counter status after seven years on the market. On February 15th, a joint panel of two FDA advisory committees voted unanimously to recommend Narcan's approval for over-the-counter status, with committee members forcefully underscoring the necessity of the treatment's broad availability.[17] The FDA is expected to issue its decision with

[15] 2020 HRT Order; 2022 HRT Order.

[16] Timing of FDA approval subject to FDA process and discretion.

[17] Press Release, *Emergent BioSolutions Reports FDA Advisory Committees' Unanimous Vote in Favor of NARCAN® (naloxone HCl) Nasal Spray for Over-the-Counter Use* (Feb. 15, 2023), https://investors.emergentbiosolutions.com/news-releases/news-release-details/emergent-biosolutions-reports-fda-advisory-committees-unanimous; U.S. Food & Drug Admin., *Joint Meeting of the NDAC and the AADPAC*, (….continued)

respect to this application by the end of March.[18] Once OTC Narcan is approved, it is expected that the existing prescription generic versions will also switch to over the counter. In addition, one company, Pocket Naloxone, intends to submit a New Drug Application in the first half of this year for an intranasal swab product, though the path to FDA approval (including over-the-counter status) is potentially more complex than for nasal spray formulations.

12. These recent developments should save thousands of lives. But the availability of an OTC version of Narcan (and generic equivalents) or a new delivery mechanism will not obviate the need for RiVive. RiVive will be differentiated by price, which in turn increases access to this life-saving drug. Because HRT is a tax-exempt 501(c)(3) company, it will be able to offer its product at a lower price than for-profit products, including generics. The price of naloxone nasal spray devices remains stubbornly high: a twin-pack of Narcan retails for approximately $125, and the price of generic formulations remains approximately 86% that of the branded product.[19] The presence of RiVive on the market may have the additional benefit of creating downward pricing pressure that will ultimately benefit the American public. In addition, HRT intends to prioritize distribution to those that have the greatest impact on saving lives with naloxone, including harm reduction centers and Departments of Health. These organizations are also those that tend to be the most cost-sensitive.

YouTube (Feb. 15, 2023), https://www.youtube.com/watch?v=QTFU0wHVotM, ("For the sake of the public and saving lives, I believe this medication should be available over the counter to the public as soon as possible.") ("The evidence is compelling that the benefits [of over-the-counter status] clearly outweigh the risks; the urgency [of approval] is paramount.") ("This is a huge public health benefit that is way overdue.").

[18] Press Release, *Emergent BioSolutions Announces U.S. FDA Acceptance and Priority Review of Supplemental New Drug Application for Over-the-Counter NARCAN® (naloxone HCl) Nasal Spray* (Dec. 6, 2022), https://investors.emergentbiosolutions.com/news-releases/news-release-details/emergent-biosolutions-announces-us-fda-acceptance-and-priority.

[19] Wholesale Acquisition Cost quoted by AnalySource®.

13. By this motion, the Debtors are seeking approval to enter into and perform under the 2023 HRT Agreement, pursuant to which the Debtors would provide up to an additional $9 million of funding to enable HRT to prepare for production, marketing, and distribution of RiVive. More specifically, HRT requires additional funding in order to conduct ongoing stability and reliability studies to support commercial shelf-life, pay certain manufacturing site readiness fees, purchase intranasal devices and vials, and satisfy third-party service provider, labor, and marketing and sales development expenses. The Debtors' commitments would be subject to HRT satisfying two milestones. The initial $5 million would be due upon the issuance of binding purchase orders for the intranasal delivery devices to cover the second half of first-year product quantities for RiVive, with the remaining $4 million due upon commencement of manufacturing of the RiVive product by HRT's contract manufacturer for subsequent distribution and commercial sale.

14. Simply put, HRT requires a modest amount of additional financing in order to deliver lower-cost, OTC naloxone to individuals and communities that need it. Without the Debtors' support, there can be no guarantee when – or even if – HRT will be able to bring RiVive to market. And helping to commercialize RiVive is in the Debtors' best interest as well, as support for OTC naloxone is one of three key initiatives (the "**Public Health Initiatives**" or "**PHI**") that the Debtors are pursuing to advance meaningful solutions to the opioid crisis.[20] The Debtors believe that the Public Health Initiatives will provide billions of dollars of value to the

[20] The other two principal Public Health Initiatives are the development of emergency opioid overdose treatments containing the opioid antagonist nalmefene and the development and distribution of a generic version of Suboxone® tablets, a leading opioid addiction treatment consisting of a combination of buprenorphine and naloxone. The Debtors obtained FDA approval for a vial form of nalmefene on February 8, 2022, and approval for their generic Suboxone in 2020.

American public.[21] Their true value, however, is the immeasurable impact these medicines can have in improving or saving lives. The Debtors therefore submit that entry into and performance under the 2023 HRT Agreement should be approved at this time.

Basis for Relief Requested

15. Bankruptcy Code section 363(b)(1) empowers the Court to authorize a debtor to "use, sell, or lease, other than in the ordinary course of business, property of the estate." To approve the use of estate property under section 363(b)(1) of the Bankruptcy Code, the Second Circuit requires a debtor to show that the decision to use the property outside of the ordinary course of business was based on the debtor's sound business judgment in light of "all salient factors" relating to the bankruptcy case. *Comm. of Equity Sec. Holders v. Lionel Corp. (In re Lionel Corp.)*, 722 F.2d 1063, 1070-71 (2d Cir. 1983) ("The rule we adopt requires that a judge determining a § 363(b) application expressly find from the evidence presented before him at the hearing a good business reason to grant such an application."); *In re Ionosphere Clubs, Inc*., 100 B.R. 670, 675 (Bankr. S.D.N.Y. 1989); *see also In re MF Glob. Inc.*, 467 B.R. 726, 730 (Bankr. S.D.N.Y. 2012) ("Although not specified by section 363, the Second Circuit requires that transactions under section 363 be based on the sound business judgment of the debtor or trustee.").

16. Section 105(a) of the Bankruptcy Code provides that the "court may issue any order, process, or judgment that is necessary or appropriate to carry out the provisions of this title." 11 U.S.C. § 105(a). Pursuant to section 105(a), orders are appropriate where they are essential to the debtor's reorganization efforts and do not pose a burden on the debtor's creditors.

[21] *E.g.*, Press Release, *Purdue Pharma L.P. Files Broadly Supported Plan of Reorganization* (Mar. 16, 2021), https://www.purduepharma.com/news/2021/03/16/purdue-pharma-l-p-files-broadly-supported-plan-of-reorganization/.

See U.S. Lines, Inc. v. Am. S.S. Owners Mut. Prof. & Indem. Ass'n (In re U.S. Lines, Inc.), 197 F.3d 631, 640 (2d Cir. 1999); *Momentum Mfg. Corp. v. Emp. Creditors Comm. (In re Momentum Mfg. Corp.)*, 25 F.3d 1132, 1136 (2d Cir. 1994) ("It is well settled that bankruptcy courts are courts of equity, empowered to invoke equitable principles to achieve fairness and justice in the reorganization process.").

17. Under the unusual circumstances of these Cases, the "salient factors" considered when evaluating the Debtors' business judgment, and whether the Debtors' decision to fund HRT's efforts would aid the Debtors' reorganization, must include how funding HRT would benefit all of the Debtors' contingent creditors and the American public at large. Judge Drain previously observed that "the Debtors' cases are highly unusual" in that "the Debtors are largely in a [sui generis] position whereby they have already agreed to turn over all of their value to their creditors," Hr'g Tr. 159:16-19 (Nov. 19, 2019), and that "this is a fundamentally public health crisis driven case where the claimants, in one sense, can be almost every citizen in the country." Id. at 159:9-12. As a result, the Court concluded that it should consider "how the public at large is to benefit" from a request by the Debtors to use property outside of the ordinary course of business. Id. at 160:17-20.

18. The Debtors' decision to support HRT's efforts to make OTC naloxone available at low cost across the U.S. is a sound exercise of the Debtor's business judgment that will facilitate and progress an initiative that could save thousands of lives.

The Debtors Have Provided Financial Support to HRT Since 2018

19. Since September of 2018, the Debtors have continued to provide modest but vital financial support to HRT in an effort to advance meaningful solutions to the opioid crisis. Purdue made its initial decision to fund HRT, and its later decisions to provide additional

funding, after careful evaluation of, among other things, the critical need for OTC naloxone, the close fit between HRT's and Purdue's PHI goals, detailed supporting budgets and development timelines, Purdue's own financial position, and HRT's capabilities and prospects of success. Before making each additional contribution to HRT, Purdue carefully evaluated HRT's progress toward bringing OTC naloxone to market, and how Purdue's contribution would allow HRT to achieve concrete milestones on the path to that goal. The Debtors' sophistication in pharmaceutical development also informed their assessment of HRT's funding proposals and the structure of the resulting funding agreements.

HRT Requires Additional Near-Term Funding

20. A grant of FDA approval for RiVive would mark a successful end to over six years of product development efforts. However, HRT requires additional assistance to reach the ultimate goal of getting FDA approved, lower-cost OTC naloxone into the market. The Debtors believe that approval of the Motion will materially advance those efforts. As was the case under the Prior HRT Agreements, the amount requested is based on a detailed budget and timeline, and the Debtors' obligation to make future milestone payments under the 2023 HRT Agreement is contingent on HRT achieving appropriate milestones. The Milestone Events and associated Milestone Payments are:

Milestone Event	Milestone Payment	Expected Milestone Achievement/ Expected Payment Date
Issuance of binding purchase order to AptarGroup, Inc. for devices to cover second half of first year Product quantities for subsequent distribution and commercial sale.	$5,000,000	Targeted completion date: March 15, 2023 Targeted Payment Due Date: April 1, 2023 (Within ten (10) days after HRT delivers a written notice to PPLP that the applicable milestone has been met)
Start of manufacturing of Product at Catalent Pharma Solutions, LLC for subsequent	$4,000,000	Targeted completion date: June 19, 2023 Targeted Payment Due Date: July 1, 2023 (Within ten (10) days after HRT delivers a

distribution and commercial sale.		written notice to PPLP that the applicable milestone has been met)

21. The timing and amount of the Milestone Payments are structured such that the amount of each Milestone Payment is sufficient only to bridge HRT to the next Milestone Event. HRT does not maintain a sufficient amount of excess cash or a line of credit that could provide a cushion in the event that the Debtors do not or cannot make an anticipated Milestone Payment.

If the Motion Is Denied, HRT Is Unlikely to Secure Timely Alternative Financing

22. The Debtors remain the only source of funding for HRT to date. The 2023 HRT Agreement and the Prior HRT Agreements require HRT to "use commercially reasonable efforts (taking into account the applicable global and local economic, health/pandemic and market conditions, as well as availability of funding) to obtain funding from third parties . .."[22] However, despite HRT's ongoing efforts, the Debtors understand that no alternative funding has been made available.

23. At least five factors help explain HRT's lack of additional outside funding sources to date despite the many voices supporting its life-saving mission. First, drug development is expensive, and only the very largest philanthropies have the capacity to contribute millions of dollars of capital. There are no large non-profit or charitable organizations (e.g., the American Cancer Society, which gathers donations for cancer research and therapies) dedicated to supporting the development of rescue drugs for people with substance use disorders. Second, most philanthropic organizations are more accustomed to funding drug distribution (e.g., anti-malarial medicines) but not to the regulatory and scientific complexity inherent in the highly technical process of drug development. The lack of pharmaceutical development subject matter

[22] 2020 HRT Agreement ¶ 4.2(D); 2022 HRT Agreement ¶ 4.2(D).

expertise within philanthropic organizations makes it particularly difficult for these organizations to evaluate the regulatory risk surrounding the development and ultimate FDA approval of regulated consumer healthcare products. Third, there is very little precedent for nonprofit pharmaceutical companies. To the Debtors' knowledge there are currently only two other nonprofit pharmaceutical companies with demonstrable drug development experience, Medicines360, which is focused exclusively on women's health, and CivicaRx, a nonprofit producing drugs to address the in-hospital drug shortage crisis, neither of which is involved with developing overdose reversal products. The lack of precedent adds a further element of uncertainty to any decision by a philanthropic organization to provide financial support to HRT. Fourth, many of the largest philanthropic organizations (e.g., the Bill and Melinda Gates Foundation) have a global focus, rendering U.S.-centric efforts less attractive to them. Finally, there are limited opportunities for direct support from state or federal agencies. In addition, HRT's corporate model makes the company unattractive to debt financing, as HRT is not expected to generate excess funds to service interest expense or repay principal due to its mission to distribute its product at low cost or for free.

24. The Debtors appreciate the importance of OTC naloxone from a public health perspective and have been uniquely positioned to provide financial support to HRT. As a pharmaceutical company with sophistication in drug development, the Debtors understand the regulatory and scientific complexity associated with HRT's mission and appreciate the value of HRT's unparalleled experience transitioning prescription medications to OTC. The Debtors have the financial wherewithal to make a multi-million dollar contribution and are not limited by competing charitable demands or geographic scope in the same way that philanthropic organizations may be. Moreover, there is no expectation that a contribution to HRT would ever

be paid back, which makes it unlikely that other for-profit pharmaceutical companies will be interested in lending their support.

25. It is possible that HRT may be more attractive to other third-party sources of capital once it has demonstrated commercial readiness for RiVive. HRT has been in contact with high net worth individuals, institutional banks, and other organizations in an attempt to access additional capital to help fund scale-up for distribution and commercial sale, further decrease the price of RiVive once approved, and increase the number of doses of RiVive that may be distributed freely. In addition, HRT has begun to engage in discussions regarding advance purchases of RiVive with some state agencies. Once RiVive has been approved by the FDA and funds can be allocated to manufacturing without the associated regulatory risk now present, the overall risk-benefit profile of financing HRT should tilt more favorably toward HRT obtaining alternative funding sources. However, the Debtors believe that a delay in preparation for commercial launch at this time for lack of third-party financial support would only serve to seriously undermine HRT's credibility as a company ready to launch its products, dramatically decrease its fundraising capability, and indefinitely delay access to lower-cost, OTC naloxone for the people who need it most urgently.

The Relief Requested Is Limited in Scope

26. As discussed above, if this Motion is granted, the Debtors will be obligated to fund—in two installments and subject to milestones—a maximum of $9 million under the 2023 HRT Agreement, which would enable HRT to prepare for production, marketing, and distribution of RiVive. The Debtors will not be obligated to purchase any product. The milestones contained in the 2023 HRT Agreement provide appropriate checks on the Debtors' funding requirements if HRT encounters any future setbacks or delays. The Debtors are free to

assign their commitment to any other party. Finally, certain creditor protections and accommodations that were present in the 2022 HRT Agreement, including that HRT will return Purdue's prior contributions and that Purdue will be entitled to 40% of HRT's equity interests (an increase from 20% in the 2020 HRT Agreement) if HRT is no longer organized for charitable or public benefit purposes, or no longer qualifies as any of a nonstock corporation, a benefit corporation, or another form of entity acceptable to PPLP, remain in the 2023 HRT Agreement.[23]

Waiver of Stay Under Bankruptcy Rule 6004(h)

27. The Debtors also request that, to the extent applicable to the relief requested in this Motion, the Court waive the stay imposed by Bankruptcy Rule 6004(h), which provides that "[a]n order authorizing the use, sale, or lease of property other than cash collateral is stayed until the expiration of 14 days after entry of the order, unless the court orders otherwise." Fed. R. Bankr. P. 6004(h). The Debtors respectfully request that the Court waive the 14-day stay imposed by Bankruptcy Rule 6004(h), as the nature of the relief sought herein justifies immediate relief.

Notice

28. Notice of this Motion will be provided as to (a) the entities on the Master Service List (as defined in the *Second Amended Order Establishing Certain Notice, Case Management, and Administrative Procedures* entered on November 18, 2019 [ECF No. 498] and available on the Debtors' case website at https://restructuring.ra.kroll.com/purduepharma) and (b) any person or entity with a particularized interest in the subject matter of this motion (the "**Notice Parties**"). The Debtors respectfully submit that no further notice is required.

[23] To be clear, no one associated with HRT has ever expressed any interest in converting HRT to a for-profit business.

No Prior Request

29. The Debtors have not previously sought the relief requested herein from the Court or any other court.

[Remainder of Page Intentionally Left Blank]

WHEREFORE, the Debtors respectfully request that the Court enter the proposed form of order, substantially in the form attached hereto, granting the relief requested herein and such other relief as the Court deems appropriate under the circumstances.

Dated: February 28, 2023
New York, New York

DAVIS POLK & WARDWELL LLP

By: */s/ Eli J. Vonnegut*

DAVIS POLK & WARDWELL LLP
450 Lexington Avenue
New York, New York 10017
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Marshall S. Huebner
Benjamin S. Kaminetzky
Eli J. Vonnegut
Christopher S. Robertson

Counsel to the Debtors
and Debtors in Possession

Exhibit A

Proposed Order

UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re: **PURDUE PHARMA L.P., *et al*.,** **Debtors.**[1]	**Chapter 11** **Case No. 19-23649 (SHL)** **(Jointly Administered)**

ORDER AUTHORIZING DEBTORS TO ENTER INTO FUNDING AGREEMENT

Upon the motion (the "**Motion**")[2] of Purdue Pharma L.P. and its affiliates that are debtors and debtors in possession in these proceedings (collectively, the "**Debtors**") for entry of an order, pursuant to sections 105(a) and 363 of the Bankruptcy Code, Bankruptcy Rules 6003 and 6004 and Rule 9013-1 of the Local Bankruptcy Rules for the Southern District of New York (the "**Local Rules**"), authorizing the Debtors to enter into a funding agreement with Harm Reduction Therapeutics, Inc. ("**HRT**"), as more fully described in the Motion; and the Court having jurisdiction to consider the Motion and the relief requested therein pursuant to 28 U.S.C. §§ 157(a)-(b) and 1334(b) and the Amended Standing Order of Reference M-431, dated January 31, 2012 (Preska, C.J.); and consideration of the Motion and the relief requested therein being a core

[1] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

[2] Unless otherwise defined herein, each capitalized term shall have the meaning ascribed to such term in the Motion.

proceeding under 28 U.S.C. § 157(b); and venue being proper before the Court pursuant to 28 U.S.C. §§ 1408 and 1409; and due and proper notice of the Motion having been provided to the Notice Parties, and it appearing that no other or further notice need be provided; and the Court having reviewed the Motion [and held a hearing to consider the relief requested in the Motion (the "**Hearing**")]; and it appearing that the proposed funding agreement was negotiated and entered into at arms-length and in good faith; and, after due deliberation, the Court having determined that the legal and factual bases set forth in the Motion and at the Hearing establish good and sufficient cause for the relief granted herein, that entry into the funding agreement is a proper exercise of business judgment in the context of these cases, and that the relief requested is in the best interests of the Debtors and their estates; now, therefor;

IT IS HEREBY ORDERED THAT

1. The Motion is hereby granted as set forth herein.

2. Pursuant to sections 105(a) and 363(b) of the Bankruptcy Code, the Debtors are authorized to enter into and perform under the 2023 HRT Agreement, including, subject to satisfaction of the First Milestone Event, to make the $5 million Milestone Payment in respect of the First Milestone Event and, subject to the satisfaction of the Second Milestone Event, to make the $4 million Milestone Payment in respect of the Second Milestone Event, in each case in accordance with the terms of the 2023 HRT Agreement.

3. Within 20 days of the end of each month, the Debtors shall provide each of the Committee and the Ad Hoc Committee with a copy of the monthly written report provided by HRT to PPLP pursuant to Section 2.5 of the 2023 HRT Agreement.

4. Any Bankruptcy Rule (including, but not limited to, Bankruptcy Rule 6004(h)) or Local Rule that might otherwise delay the effectiveness of this Order is hereby waived, and the terms and conditions of this Order shall be effective immediately and enforceable upon its entry.

5. The contents of the Motion and the notice procedures set forth therein are good and sufficient notice and satisfy the Bankruptcy Rules and the Local Rules, and no other or further notice of the Motion or the entry of this Order shall be required.

6. In the event that the Debtors seek future authorization to make additional payments to HRT not authorized under this Order, nothing herein shall limit or otherwise modify any party's right to object to the granting of such relief on any ground or the Court's evaluation of any such objection.

7. The Court shall retain jurisdiction to hear and determine all matters arising from or related to the implementation, interpretation and enforcement of this Order.

White Plains, New York
Dated: _____, 2023

THE HONORABLE SEAN H. LANE
UNITED STATES BANKRUPTCY JUDGE

Exhibit B

Form of Funding Agreement

Execution Version

FUNDING AGREEMENT

This Funding Agreement ("Agreement") is dated as of March [•], 2023 between Harm Reduction Therapeutics, Inc., a nonstock Maryland not-for-profit corporation ("HRT"), and Purdue Pharma L.P., a Delaware limited partnership ("PPLP"). (As used herein, each of HRT and PPLP is referred to as a "Party" and collectively as the "Parties.")

WHEREAS, HRT is interested in marketing and distributing solely in the Territory a single dose, over-the-counter, naloxone intranasal spray device intended to treat opioid overdoses (the "Product");

WHEREAS, PPLP is committed to addressing opioid use disorder and has provided financial contributions, technical expertise and rights to data to HRT since 2018 to support HRT's development of the Product;

WHEREAS, in March 2022 the Parties entered into an Amended and Restated Funding Agreement (the "Amended and Restated Funding Agreement"), providing for, among other things, funding for the development, marketing, and seeking Regulatory Approval of the Product so that ultimately HRT may provide the approved Product to first responders, government agencies, not-for-profit entities, communities and individuals (collectively, "Contemplated Product Users");

WHEREAS, PPLP and HRT wish to enter into this Agreement pursuant to which PPLP will provide funding for readiness of the Product for distribution and sale, subject to the terms and conditions set forth below.

NOW THEREFORE, HRT and PPLP, intending to be legally bound, hereby agree as follows:

ARTICLE I
DEFINITIONS

1.1 "Approval Order" means an order of the Bankruptcy Court, in form and substance reasonably acceptable to the Parties, approving PPLP's entry into this Agreement.

1.2 "Bankruptcy Court" means the United States Bankruptcy Court for the Southern District of New York having jurisdiction over the Chapter 11 Cases.

1.3 "Chapter 11 Cases" means the bankruptcy cases filed on September 15, 2019 by PPLP and certain of its affiliates under Chapter 11 of the United States Code in the Bankruptcy Court and jointly administered under Case No. 19-23649 (SHL).

1.4 "Claim" means, with respect to any Person, any claim, demand, action, proceeding, judgment, damage, loss, cost, expense, or liability whatever, incurred or suffered by or brought, made, or recovered against such Person (whether or not presently ascertained, immediate, future, or contingent) arising out of or relating to the sale or use of the Product by HRT or by any holder or user of the Product that in the chain of distribution came from or through HRT.

1.5 "Cost" means HRT's cost of goods sold for PPLP Funded Products (as defined in Section 2.3), on a fully absorbed basis, including general and administrative expenses, in accordance with United States generally accepted accounting principles, and any federal excise taxes and other federal, state and local taxes, as applicable.

1.6 "FDA" means the United States Food and Drug Administration, or any successor entity.

1.7 "GMP" means, as applicable, the then-current good manufacturing practices set forth in (a) for medical devices, the quality system regulation 21 C. F. R. Part 820,and (b) for finished drug products, 21 C.F.R. Parts 210 and 211 , as such practices may be updated from time to time.

1.8 "Milestone Event" means any of the events set forth in Section 2.2 under the column "Milestone Event."

1.9 "Milestone Payment" means any of the payments set forth in Section 2.2 under the column "Milestone Payment."

1.10 "NDA" means a New Drug Application as defined in the Federal Food, Drug and Cosmetic Act.

1.11 "Person" means any natural person, corporation (including any non-profit corporation), cooperative, company, foundation, general partnership, limited partnership, limited liability company, unlimited liability company, joint venture, estate, trust, association, organization, labor union, governmental body, custodian, nominee and any other individual or entity.

1.12 "Product Registration" means, in relation to the Product, an NDA that has been approved by the FDA, including any amendments or supplements.

1.13 "Regulatory Approval" means drug approval and all other approvals necessary for the distribution of Product in the Territory.

1.14 "Regulatory Authority" means any federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.15 "Regulatory Materials" means regulatory applications, submissions, notifications, communications, correspondence, registrations, drug approvals or other filings made to, received from or otherwise conducted with a Regulatory Authority to develop, manufacture, market, sell or otherwise distribute Product in the Territory.

1.16 "RiVive" means the proposed name of 3.0 mg intranasal Product (as such name may be amended from time to time).

1.17 "Territory" means the United States of America, including its territories and possessions.

1.18 "Unit" means one package containing two (2) RiVive intranasal naloxone devices.

ARTICLE II
EFFECTIVENESS; FINANCIAL ASSISTANCE

2.1 **Effectiveness**. This Agreement shall, upon entry of the Approval Order by the Bankruptcy Court and execution and delivery by the Parties, become effective and binding upon the Parties (such date, the "Effective Date").

2.2 **Financial Assistance; Milestone Payments**.

(a) HRT will use commercially reasonable efforts to prepare for the commercial readiness and commercial launch of the Product in the Territory and will use the funding provided by PPLP and referenced below only for (i) additional studies of the Product in response to regulatory requirements, (ii) improvement and changes to the Product, (iii) expenses incurred from manufacturers of Product components and service providers in preparation for freight, warehousing, distribution, commercial launch and supply of the Product, including overhead expenses, (iv) compensation of HRT's employees that are involved in the development, manufacture, marketing, sale, supply or distribution of the Product in the Territory, (v) development and commercial readiness consultants, and (vi) general working capital, including legal, insurance, financing and compliance costs and expenses. For clarity, any reference in this Agreement to commercial sale of Product or commercialization of Product shall include production and distribution of Product for charitable purposes.

(b) PPLP hereby agrees to provide funding to HRT in the form of Milestone Payments, payable after the achievement of certain Milestone Events. The Milestone Payments are described below:

Milestone Event	Milestone Payment	Expected Milestone Achievement/ Expected Payment Date
Issuance of binding purchase order to AptarGroup, Inc. for devices to cover second half of first year Product quantities for subsequent distribution and commercial sale	$5,000,000	Targeted completion date: March 15, 2023 Targeted Payment Due Date: April 1, 2023 (Within ten (10) days after HRT delivers a written notice to PPLP that the applicable milestone has been met)
Start of manufacturing of Product at Catalent Pharma Solutions, LLC for subsequent distribution and commercial sale	$4,000,000	Targeted completion date: June 19, 2023 Payment Due Date: July 1, 2023 (Within ten (10) days after HRT delivers a written notice to PPLP that the applicable milestone has been met)

The above referenced milestone achievement dates are expected dates only, are not intended to be deadlines and do not trigger any Milestone Payments (unless the Milestone Event has actually occurred). Each Milestone Payment is a one-time only payment based on the achievement of the Milestone Event; provided, that no Milestone Payment will be made unless the previously listed Milestone Event has been achieved. Promptly after HRT determines that it has achieved a Milestone Event, HRT shall provide notice thereof to PPLP in accordance with Section 9.2 hereof, which notice shall include sufficient detail of the achievement of such Milestone Event to enable PPLP to verify whether it agrees with HRT's determination. If, after receipt of the foregoing notice, PPLP agrees, reasonably and in good faith, that a Milestone Event has been achieved by HRT, PPLP shall pay the corresponding Milestone Payment to HRT within the time period set forth in the above chart after the date the Milestone Event was achieved or at such later time as HRT may request; provided, in no event will the Milestone Payment be due prior to the corresponding expected Payment Due Date set forth in the above chart. If PPLP does not agree that a Milestone Event has been achieved, the Parties will work in good faith to resolve any such dispute.

The aggregate amount of the Milestone Payments shall not exceed nine million dollars ($9,000,000).

Notwithstanding the foregoing, (i) if HRT licenses from a third party an FDA-approved product (i.e., with a Regulatory Approval) to serve as the Product, PPLP shall not make the Milestone Payments referred to above, but the Parties will discuss in good faith any alternative funding that may be required by HRT to obtain approval for the Product (i.e., with a Regulatory Approval) to be distributed over-the-counter and (ii) if HRT receives any funding from any third party that is based on a new request or application made or submitted solely after the Effective Date to fund the distribution and sale of the Product, and such third party financing is received, such third party funding will reduce the amount of subsequent unpaid Milestone Payments by the amount of such third party funding (with the understanding that it will not reduce any other Milestone Payment hereunder and that HRT will have no obligation to return any Milestone Payments previously paid to HRT).

2.3 **Financial Assistance for HRT's Manufacture and Distribution of Product.**

As part of PPLP's public health initiatives, after FDA Regulatory Approval of HRT's NDA for the Product, PPLP may provide funds to HRT to enable HRT to manufacture Units of Product ("PPLP Funded Products") so that such Units can be donated free of charge or sold at Cost to Contemplated Product Users.

In the event PPLP does provide funding to HRT to enable HRT to manufacture PPLP Funded Products, at least two (2) months prior to each calendar quarter HRT and PPLP will agree upon a written annual forecast of PPLP Funded Products to be manufactured and donated free of charge or sold at Cost to the Contemplated Product Users as follows:

(i) a binding forecast for the quantities of PPLP Funded Products to be manufactured and donated free of charge or sold at Cost to the Contemplated Product

Users during the upcoming calendar quarter, with projected delivery dates, sizes, strengths and ultimate destinations, as well as other relevant manufacturing and delivery information. PPLP shall fund one hundred percent (100%) of the Cost of such agreed upon forecast of PPLP Funded Products;

(ii) an estimate of the quantities of PPLP Funded Products to be manufactured and donated free of charge or sold at Cost to the Contemplated Product Users during the calendar quarter following the upcoming calendar quarter. PPLP shall fund at least fifty percent (50%) of the Cost of such forecast of PPLP Funded Products; and

(iii) a non-binding estimate of the forecast of PPLP Funded Products HRT intends to manufacture and which will be donated free of charge or sold at Cost to the Contemplated Product Users for the third and fourth calendar quarters of such forecast.

Each subsequent written forecast shall update the prior estimate and include an estimate of requirements for the next additional calendar quarter, so that estimates for a rolling one- (1-) year period are provided.

For avoidance of doubt, HRT shall not be obligated to produce and deliver any PPLP Funded Product to any Contemplated Product User unless PPLP has funded the applicable verifiable Cost related thereto in sufficient time to allow manufacture of such Funded Product in accordance with the forecasts set forth above or as otherwise agreed to by the Parties (at an agreed upon rate reasonably calculated to allow HRT to diligently produce the Product). Any payments received by HRT in advance of the future donation or sale of PPLP Funded Products will be credited to the funding of the next forecasted quantities of PPLP Funded Products.

2.4 **Audit Rights.**

(a) Commencing as of the Effective Date and ending on the earliest of (i) termination of this Agreement, (ii) the third anniversary of the latest delivered Milestone Payment, (iii) or the sixth anniversary hereof if no Milestone Payment has been made by such time, PPLP shall have the right to conduct audits of HRT's data and its books and records to reasonably determine whether Milestone Events have been achieved.

(b) Commencing as of the Effective Date, PPLP shall have the right to conduct audits of the books and records of HRT not more than once during each calendar year until three (3) years after the termination of this Agreement, to verify that the funds provided by PPLP have been used in a manner consistent with Section 2.2(a) and HRT's Cost related to Units of Product.

(c) PPLP may exercise the audit rights described in (a) and (b) above by providing written notice to HRT and any such audit shall be conducted during normal business hours. HRT shall make available to PPLP such accounting and other books and records, reasonably requested by PPLP to exercise its rights hereunder.

2.5 **Reports**.

At least once during each month until the end of the first full year following commercial launch of the Product for distribution and sale, HRT shall provide a written report to PPLP regarding its progress toward (i) achieving the Milestone Events, including an update on the Expected Milestone Achievement Date for each such Milestone Event and (ii) following achievement of the Milestone Events, details regarding the launch of the Product for commercial distribution and sale, and (iii) following commercial launch of the Product for commercial distribution and sale, details regarding distribution of the Product to Contemplated Product Users. Each report will account for HRT's expenditures of funding provided by PPLP allocated among the categories set forth in Section 2.2(a). HRT shall also report on any funding that it received from third parties in connection with the Product, promptly after it becomes aware of such funding.

ARTICLE III
INTELLECTUAL PROPERTY

3.1 **Ownership of Data; Product Registrations**. HRT will be the sole owner of (a) all the data generated by HRT supporting development and registration of the Product, (b) the database of such data, (c) all Regulatory Approvals and Product Registrations in the Territory, and (d) all Regulatory Materials, except as may be set forth in any other agreement between the Parties.

3.2 **IP Assignment**. HRT and its affiliates may assign, sell, license or otherwise transfer any intellectual property related to the Product, only with the prior written consent of PPLP, such consent not to be unreasonably withheld or denied. Any purported assignment, sale or transfer of rights in or to any intellectual property in contravention of this Section 3.2 shall be null and void ab initio. The restrictions set forth in this Section 3.2 shall expire on June 30, 2039. PPLP hereby consents to the grant, by HRT, of a non-exclusive license to the Producers and Suppliers (as defined below) related to the underlying intellectual property of the Product, for the limited purpose of producing, manufacturing, packaging and supplying the Products for HRT. "Producers and Suppliers" means the producers and suppliers of HRT listed in Exhibit A hereto.

ARTICLE IV
REPRESENTATIONS, WARRANTIES AND COVENANTS

4.1 **Mutual Representations and Warranties**. Each Party hereby represents and warrants to the other Party as of the date hereof and as of the Effective Date as follows:

A. **Authority**. It is validly existing and in good standing or active under the laws of the jurisdiction of incorporation or organization, has the power and authority to enter into this Agreement and has taken all necessary actions on its part required to authorize the execution and delivery of this Agreement. This Agreement has been duly executed and delivered by such Party and constitutes the valid and

binding obligation of such Party, enforceable against it in accordance with its terms except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles. The execution, delivery and performance of this Agreement has been duly authorized by all necessary action on the part of such Party, its officers, directors, members and/or managers, as applicable.

B. **No Conflict**. The execution, delivery and performance of this Agreement by such Party does not, to such Party's knowledge, violate any material law or regulation or any order of any court, governmental body or administrative or other agency having authority over them. It is not currently a party to any material agreements, oral or written, that would cause it to be in breach of its obligations under this Agreement, and execution and delivery of this Agreement does not and will not conflict with, violate or breach any contractual obligations of such Party.

4.2 **HRT Representations, Warranties and Covenants**. HRT hereby further represents, warrants and covenants to PPLP that:

A. As of the Effective Date, HRT is and, during the term of this Agreement will continue to be, a nonstock corporation organized under the laws of the State of Maryland. HRT shall not contemplate pecuniary gain or profit, incidental or otherwise, and no part of the net earnings of HRT shall inure to the benefit of or be distributed to any director or officer of HRT, or to any other private person, except that HRT shall be authorized and empowered to pay reasonable compensation for services rendered and to make payments and distributions in furtherance of its charitable and/or public benefit purposes.

B. While receiving funding from PPLP under this Agreement, HRT will not participate in any lobbying activities that are prohibited by PPLP injunction(s), as delivered to HRT in writing from time to time. Advocacy by HRT before any Regulatory Authority regarding Regulatory Approval of the Product shall not be deemed to violate this Section 4.2(B).

C. HRT will manufacture PPLP Funded Products, and sell or donate PPLP Funded Products in compliance with all applicable laws, including any applicable state transparency laws and applicable GMP (as and to the extent applicable to the PPLP Funded Products).

D. HRT will use commercially reasonable efforts (taking into account the applicable global and local economic, health/pandemic and market conditions, as well as availability of funding) to obtain funding from third parties for supply readiness and launch of the Product.

E. If HRT is no longer organized for charitable or public benefit purposes or no longer otherwise qualifies as any of (i) a non-stock corporation, (ii) a benefit corporation, or (iii) another form of entity acceptable to PPLP, (x) HRT will

provide written notice to PPLP that it is no longer so organized or no longer so qualifies, (y) HRT will repay to PPLP all amounts provided to it by PPLP under this Agreement, no later than one (1) year after written request for such repayment is made by PPLP. HRT affirms, in the case of the circumstances described above in this Section 4.2(E)., (a) its obligation under the Amended and Restated Funding Agreement to repay to PPLP, no later than one (1) year after receiving PPLP's written request, all amounts provided to it by PPLP under the Amended and Restated Funding Agreement, including all cash funding provided by PPLP to HRT under the Prior Agreements (as defined in the Amended and Restated Funding Agreement), and (b) that, in PPLP's sole discretion but subject to HRT's receipt of any necessary governmental or regulatory approvals and compliance with applicable laws, PPLP will be entitled to forty percent (40%) of all of the equity interests in HRT.

ARTICLE V
TERM AND TERMINATION

5.1 **Term**. This Agreement shall become effective on the Effective Date and shall remain in effect until terminated pursuant to Sections 5.2, 5.3, 5.4, or 5.5.

5.2 **Termination for Material Breach**. Either Party shall have the right to terminate this Agreement in the event that the other Party commits a material breach of this Agreement by giving written notice of such breach to the breaching Party. Termination shall be effective ninety (90) days after the giving of such notice unless the breaching Party has remedied the breach within such ninety (90) day period.

5.3 **Termination for Bankruptcy or Change of Status**. PPLP may terminate this Agreement upon notice to HRT if HRT becomes insolvent, makes any assignment for the benefit of its creditors, is placed in receivership, liquidation or bankruptcy or if it is no longer organized for charitable, or public benefit purposes or no longer otherwise qualifies as any of (i) a non-stock corporation, (ii) a benefit corporation, or (iii) another form of entity acceptable to PPLP. PPLP's right to terminate under this Section 5.3 is in addition to any of its rights under Section 4.2(E). of this Agreement.

5.4 **Termination by PPLP**. PPLP may terminate this Agreement, upon (x) fifteen (15) days' prior written notice if HRT has not achieved a Milestone Event set forth in Section 2.2 within one hundred eighty (180) days of the Targeted Completion Date set forth with respect to such Milestone Event or (y) sixty (60) days' prior written notice, if HRT has stopped using commercially reasonable efforts to prepare for commercial launch of the Product for distribution and sale in the Territory (during which sixty (60)-day period HRT may resume using such efforts and upon PPLP's reasonable satisfaction that such efforts have resumed such notice shall be withdrawn).

5.5 **Termination by HRT**. HRT may terminate this Agreement on the sixth anniversary hereof, by providing a written notice to that effect to PPLP, if no Milestone Payment has been made by such time.

5.6 **Publicity Upon Termination**. If either Party terminates this Agreement for any reason, the Parties will agree upon the wording of any public announcement of such termination and, if the Parties are unable to reach such agreement, neither Party shall release any public announcement relating to such termination without the other Party's written consent. Following any termination of this Agreement, HRT will not make any public statements about this Agreement, the circumstances surrounding the termination or the relationship between the Parties without the prior written consent of PPLP, except for any such statements required pursuant to legal process. PPLP will give HRT prior written notice of any statement it proposes to make following such termination and, except for statements made pursuant to legal process, will take into consideration any comments HRT may have with respect to such statements. Notwithstanding the above, HRT may disclose the termination of this Agreement to any of its vendors, suppliers, sales personnel, distributors, employees and other service providers.

ARTICLE VI
INDEMNIFICATION

6.1 **Indemnification by HRT**. Except as otherwise specifically provided herein, HRT shall indemnify and hold harmless PPLP and its officers, directors, agents, employees, distributors, successors and assigns from and against all Claims, actions, losses, damages, costs, expenses or other liabilities in respect of any third party Claims arising out of (a) the use, development, marketing, seeking Regulatory Approval of or distribution of the Product by HRT, (b) breach of any of HRT's material obligations under this Agreement, including HRT's representations and warranties, or (c) the willful misconduct or grossly negligent acts of HRT, or the officers, directors, employees, or agents of HRT; provided that HRT shall have no liability or indemnification obligation under this Section 6.1 arising from liabilities to third parties principally caused by the acts or omissions of PPLP.

6.2 **Limitation of Liability**. EXCEPT WITH RESPECT TO A BREACH OF THE PROVISIONS SET FORTH IN ARTICLE VII, INDEMNIFICATION OBLIGATIONS FOR THIRD PARTY CLAIMS PURSUANT TO SECTION 6.1, AND FAILURE TO COMPLY WITH THE ASSIGNMENT PREREQUISITES PURSUANT TO SECTION 3.2, NO PARTY SHALL BE ENTITLED TO RECOVER FROM ANY OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, INDIRECT OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT.

ARTICLE VII
CONFIDENTIALITY AND NONDISPARAGEMENT

7.1 **Confidentiality**. Except as otherwise agreed in writing between the Parties, the Parties will keep the terms of this Agreement confidential; provided, however, that either Party may disclose such terms (i) to the extent required by applicable law, (ii) to obtain Bankruptcy Court approval of the Approval Order or otherwise as may be reasonably required in connection with the confirmation or consummation of any plan of reorganization, (iii) as may be requested by any court appointed monitor of any PPLP injunction, or (iv) pursuant to any request for information from any other governmental entity or any compulsory legal process.

7.2 **Nondisparagement**. PPLP and HRT each agree that for a period of five (5) years from the Effective Date, neither Party will disparage, portray in a negative or false light, or take any action that would lead to unfavorable publicity for the other Party or its employees or owners, whether such disparagement, portrayal, or action is made publicly or privately, in the form of opinion or otherwise and including, without limitation, in any and all interviews, verbal statements, written materials, and electronically-displayed materials; all of the above, only to the extent that such disparagement, portrayal, publicity or action relates to this Agreement, the Parties' on-going relationship, or PPLP's funding and support for HRT's development, commercial sale or distribution of the Product. Neither Party shall be deemed to be in breach of this Section 7.2 if the alleged disparagement, portrayal, publicity or action by such Party is truthful and is made in connection with legally required testimony, pleading, investigation or any legal proceeding in front of a court, an arbitration panel or any governmental agency or entity.

ARTICLE VIII
COMMUNICATIONS, COOPERATION AND PRESENTATION OF RESEARCH

8.1 **Collaboration**. PPLP and HRT will collaborate on a public communications strategy related to FDA review and approval of NDA No. 217722 and HRT's preparation for readiness of the Product for distribution and sale and PPLP's support thereof and will align on scheduled milestones for joint communications (e.g., press releases, social media, and statements), which may include up to four (4) opportunities per year.

8.2 **Presentation of Research**. If HRT intends to present research data related to the Product at a scientific forum or other public venue, it will notify PPLP not less than forty-five (45) days in advance of such event and HRT and PPLP will discuss whether and how PPLP's support of HRT and HRT's development will be referenced; provided that no such reference may be made without PPLP's prior written consent, which will not be unreasonably withheld. HRT and PPLP will also agree upon any press releases, social media releases or other announcements proposed to be made regarding such presentation.

8.3 **Websites and Social Media**. PPLP and HRT will continue to include information about funding and support provided by PPLP on both Parties' websites and through social media channels.

ARTICLE IX
MISCELLANEOUS PROVISIONS

9.1 **Assignment**. HRT shall not assign this Agreement without PPLP's prior written consent, which consent shall not be unreasonably withheld, provided however, that no such consent will be required in connection with the sale or transfer of all or substantially all of HRT's assets, provided that the successor to HRT shall be (i) a not for profit organization, (ii) a benefit corporation or (iii) another entity reasonably acceptable to PPLP, and shall have assumed, in a writing delivered to PPLP, all of the duties and obligations of HRT and shall agree to make all of the representations and warranties and observe all of the covenants of Section 4.2. PPLP may assign this Agreement or all of its rights and may delegate any or all of its obligations hereunder, provided that no such assignment shall be binding and valid until and unless the assignee shall have assumed, in a writing delivered to HRT, all of the duties and obligations of PPLP; provided that any assignment by PPLP in connection with the consummation of a plan of reorganization of PPLP shall be deemed to have satisfied the requirement of the delivery of such a writing.

9.2 **Notices**. Any notice or other communication which shall or may be given pursuant to this Agreement shall be in writing and shall be delivered by certified mail or by facsimile transmission confirmed by certified mail, addressed to the Parties' respective addresses as set forth below:

If to HRT: Harm Reduction Therapeutics, Inc.
4800 Montgomery Lane, Suite 400
Bethesda, MD 20814
Attn: President

With a copy to: K&L Gates LLP
K&L Gates Center
210 Sixth Avenue
Pittsburgh, PA 15222-2613
Attn: Oded Green

If to PPLP: Purdue Pharma L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901
Attn: General Counsel

With a copy to: Purdue Pharma L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901
Attn: Chief Financial Officer

and

Arnold and Porter Kaye Scholer LLP
250 West 55th Street
New York, New York 10019-9710
Attn: Rory Greiss and Eric Rothman

Any Party may change its address by notice to the other Party.

9.3 **Further Assurances**. Each Party shall take all such steps, execute all such documents and do all such acts and things as may be reasonably required by the other Party to give effect to any of the transactions contemplated by this Agreement.

9.4 **Agency and Representation**. The legal relationship between the Parties shall not be construed such that any Party is deemed a partner or agent of the other Party, nor will it confer upon any Party the right or power to bind the other Party in any contract or to the performance of any obligations as to any third party. Each Party shall conduct its transactions and operations with the other as an independent contractor.

9.5 **Non-Waiver**. Neither the failure of any Party to enforce at any time any of the provisions of this Agreement nor the granting of any time or other indulgence shall be construed as a waiver of that provision or of the right of that Party thereafter to enforce that or any other provision.

9.6 **Severability**. In the event that any provision of this Agreement would be held in any jurisdiction to be invalid, prohibited or unenforceable for any reason, such provision, as to such jurisdiction, shall be ineffective, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision in any other jurisdiction. Notwithstanding the foregoing, if such provision could be more narrowly drawn so as not to be invalid, prohibited or unenforceable in such jurisdiction, it shall, as to such jurisdiction, be so narrowly drawn, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision in any other jurisdiction.

9.7 **Costs**. Each Party shall bear its own costs arising out of the negotiation and preparation of this Agreement.

9.8 **Entire Agreement**. This Agreement constitutes the entire agreement between the Parties concerning the subject matter hereof. Notwithstanding the foregoing, the Amended and Restated Funding Agreement, the Agreement dated as of July 29, 2019 and the Letter Agreement dated November 9, 2017 between the Parties will remain in full force and effect. This Agreement has no effect on the Agreement dated as of June 26, 2018, by and between HRT and Mundipharma International Corporation Limited (including its related Assignment and Bill of Sale and Assignment).

9.9 **Amendment**. This Agreement may not be amended except by a further written agreement duly executed by authorized representatives of the Parties.

9.10 **Governing Law**. This Agreement shall be governed by and construed in accordance with the laws of the State of New York without reference to its choice of law and conflicts of law provisions.

9.11 **Counterparts**. This Agreement may be executed in two or more counterparts (including by facsimile or other electronic transmission), each of which shall be deemed an original, but all of which together shall constitute a single agreement.

9.12 **Third-Party Beneficiaries**. Except as specifically provided herein, this Agreement is not intended to confer upon any non-party any rights or remedies hereunder.

9.13 **Survival**. The provisions of Section 2.4, 4.2(E). and 5.6 and Articles III, VI, VII and IX shall survive the termination of this Agreement.

9.14 **Force Majeure**. Each Party will be excused for delays in performing or from its failure to perform hereunder to the extent that the delays or failures result from causes beyond the reasonable control of such Party; provided that, in order to be excused from the delay or failure to perform, such Party much act diligently to remedy the cause of the delay or failure.

IN WITNESS WHEREOF, the parties have caused this Agreement to be signed by their duly authorized representatives as of the date first written above.

HARM REDUCTION THERAPEUTICS, INC.

BY: Michael Hufford, Ph.D.
TITLE: CHIEF EXECUTIVE OFFICER

PURDUE PHARMA L.P.

By: PURDUE PHARMA INC., ITS GENERAL PARTNER

BY:
TITLE:

EXHIBIT A
Current Producers and Suppliers

- The current supplier of the nasal spray device for the Product with which Harm Reduction Therapeutics, Inc. has an existing Master Services Agreement, dated as of September 27, 2019.

- The current producer of the Product with which Harm Reduction Therapeutics, Inc. has an existing Commercial Supply Agreement, dated as of June 30, 2022, and Master Development and Clinical Supply Agreement, dated as of June 14, 2019.

- A prospective packager of the Product with which Harm Reduction Therapeutics, Inc. is currently negotiating an agreement with respect to primary packaging, secondary packaging, and tertiary packaging for the Product.